delivery of the therapeutic substance to a vessel lumen.

REMARKS

Claims 1, 3, 4, 8, 9, 10, 11, 21, 22, 23, 24, 25, 27, and 28 are pending. Claims 2, 5, 6, 7, and 26 have been canceled. Claims 12-20 were previously canceled.

Claims 1-11 and 21-25 have been rejected under 35 U.S.C. § 112, first paragraph, and as well as the second paragraph. The term "string-like" has been removed from the claims. Claim 1 has been amended to recite "string filament." The term is well supported in the specification and does not provide new matter. For example, page 11 of the specification describes a "string monofilament 44 that can be wrapped around ... the stent." Figure 6 clearly shows a string filament wrapped around the stent. Applicants have not only described a string filament in the specification but also have illustrated a drawing of the string in Figure 6. Removal of the rejection is respectfully requested.

Claims 1-9, 11, 21, 22, 24, and 25 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Brown et al., or alternatively under 35 U.S.C. § 103(a) as being unpatentable over Brown et al.

With respect to the anticipation rejection, the Examiner has stated that "Brown et al. anticipates the claim language where the filament portion are the active agents in carriers (23, 25) of Brown and they are 'string-like' to the extent this claim language can be given patentable weight.... The active agent with carrier (23, 25) is considered to be a fiber or 'string-like' to the extent required by the present claim language." Applicants respectfully disagree. For a claim to be anticipated, every limitation of the claim must be taught by the reference. Brown et al. provide absolutely no teaching that the polymer-drug deposit has a **"string filament"** consistency, as claimed. Brown et al. teach that the active agent can be applied to the exterior

surface by spraying the tube, dipping the tube, or by other conventional methods. (*see, for example*, col. 12, lines 38-42). The active agents can be blended with polymers for sustained delivery. Such conventional methods such as dipping and spraying require the polymer-drug blend to be dissolved in a solvent, applied to the stent, and then the solvent to be evaporated to form the deposit. **Once the solvent is evaporated, the end coating does not have a "string filament" structure. Simply put, these conventional techniques do not provide for a string filament as claimed. Just because the figure shows that the deposit is in conformity with the shape of the helical groove around the perimeter of the stent does not mean that the deposit, in and of itself, is a string filament.** Spraying and dipping techniques were already known in the art and commonly used (*see, for example,* US Patent No. 5,464,650). Brown merely modified the design of the stent by adding grooves for directional drug delivery. Using a string filament with a stent for drug delivery is novel and has not been described by the references cited by the Examiner. Applicants request that the Examiner provide more than a mere conclusory statement of why the deposit of Brown et al. could possibly have a string filament structure. Since the deposit of Brown et al. is not a "string filament," claim 1 is patenatbly allowable over Brown et al. Claims 3, 4, 8, 9, 11, 21, 22, 24, and 25 depend from claim 1 and are patentably allowable for at least the same reason. Claims 5, 6, and 7 have been canceled.

With respect to the obviousness rejection, the Examiner has stated that at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to make the elements in a more solid or "string-like" nature. As noted above, nowhere in Brown et al. is "string filament" disclosed. The Examiner has not provided a secondary reference for the support of this position. Accordingly, applicants are assuming that the Examiner is taking "official notice" that the use of string filaments is common knowledge in the art and therefore "an obvious matter of design choice." In accordance with MPEP 2144.03,

"official notice unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known." As indicated by *In re Ahlert*, 424, F.2d 1088, 1091, 165 USPQ 418, 420 (CCPA 1970), the notice of facts beyond the record which may be taken by the examiner must be "capable of such instant and unquestionable demonstration as to defy dispute." As further noted by MPEP 2144.03, if the applicants adequately traverse this rejection, the Examiner **"must provide documentary evidence in the next Office action if the rejection is to be maintained."** (emphasis added). Applicants respectfully traverse the Examiner's rejection and require the Examiner to provide documentary evidence, such as in a form of an affidavit, maintaining that the use of string filaments is obvious matter of design choice to one having ordinary skill in the art. Applicants believe that use of string filaments has not been used with implantable devices, more particularly stents, for drug delivery purposes and is completely contrary to the teaching of the prior art -- namely, solution spraying and dipping techniques.

Claims 8, 11, and 22 depend from Claim 1 and are patentably allowable for at least the same reason. Removal of the rejection is requested.

Claim 10 has been rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. in view of Fischell et al. (US Patent No. 5,722,984). As indicated above, claim 1 is patentably allowable over Brown et al. Fischell et al. do the cure the previously described deficiencies of Brown et al. with respect to claim 1. Accordingly, claim 1 is allowable over the combination of the references. Claim 10 depends from Claim 1 and is allowable for at least the same reason.

Claim 23 has also been rejected as being unpatanble over Brown et al. under 35 U.S.C § 103(a). The Examiner indicated that the use of an adhesive would be an obvious choice. The

Examiner has failed to provide any documentary evidence of why this would be an obvious choice. Accordingly, the applicants transverse the Examiner's rejection and require the Examiner to provide support for this position. Brown et al. use a solution of drug and polymers for spraying or dipping. Such techniques do not require the use of adhesive because when the solvent evaporates, the polymer coating tends to stick on the surface of the stent. If Brown et al. have no need for the use of adhesives, its counter intuitive to say that an adhesive could be used with Brown et al.

In sum, it is the applicants position that Brown et al. fails to explicitly or implicitly teach a "string filament" as claimed. With respect to the obviousness rejections, applicants requests, as they are entitled to, for the Examiner to provide documentary evidence in support of his position. Withdrawal of the rejections and allowance of the claims is respectfully requested. Should the Examiner have any questions or concerns, the Examiner is invited to call the undersigned attorney of record at (415) 954-0323.

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Respectfully submitted,

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